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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,497	06/27/2002	John C. Reed	P-LJ 5137	2174
41552	7590	08/23/2005	EXAMINER	
MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122			SANG, HONG	
			ART UNIT	PAPER NUMBER
			1643	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/030,497

Applicant(s)

REED, JOHN C.

Examiner

Hong Sang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 51-88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 51-88 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

**RE: Reed**

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- |           |   |
|-----------|---|
| Groups I  | Claims 51-54 and 58-63, drawn in part to a method for determining the risk of tumor recurrence or spread in a patient suffering from prostate cancer, said method comprising determining a BAG gene expression level, wherein the BAG gene expression level is determined by measuring a BAG protein level.   |
| Group II  | Claim(s) 51-52, 55-60 and 63, drawn in part to drawn in part to a method for determining the risk of tumor recurrence or spread in a patient suffering from prostate cancer, said method comprising determining a BAG gene expression level, wherein the BAG gene expression level is determined by measuring the level of a nucleic acid which encodes said BAG protein. |
| Group III | Claims 64-68 72-77, drawn in part to a method for determining a prognosis of survival in a patient suffering from prostate cancer, said method comprising determining a BAG gene expression level, wherein the  |

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BAG gene expression level is determined by measuring a BAG protein level.

Group IV claims 64-66, 69-74, and 77, drawn in part to a method for determining a prognosis of survival in a patient suffering from prostate cancer, said method comprising determining a BAG gene expression level, wherein the BAG gene expression level is determined by measuring the level of a nucleic acid which encodes said BAG protein.

Group V claims 78-80, 84-88, drawn in part to a method for monitoring the effectiveness of a course of treatment for a patient suffering from prostate cancer, said method comprising determining a BAG gene expression level, wherein the BAG gene expression level is determined by measuring a BAG protein level.

Group IV claims 78, 81-86, drawn in part to a method for monitoring the effectiveness of a course of treatment for a patient suffering from prostate cancer, said method comprising determining a BAG gene expression level, wherein the BAG gene expression level is determined by measuring the level of a nucleic acid which encodes said BAG protein.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature linking the Groups I-II appears to be the BAG gene expression level as a tumor

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marker. The BAG gene expression level as a tumor marker cannot be a special technical feature under PCT Rule 13.2 because it is shown by Krajewski et al. (Endocrine-Related Cancer, Mar.6 (1): 29-40, 1999, IDS) and Froesch et al. (J. Biological Chemistry, 273 (19) 11660-11666, 1998) in the prior art. Krajewski et al. teach the BAG gene expression level as a breast cancer marker (see pages 34-36), and Froesch et al. teach that BAG-1L plays an important role in prostate cancer (see abstract), therefore the technical feature linking the inventions is not novel and does not provide contribution over the prior art. Therefore, unity of invention is lacking and the inventions are deemed to be separate.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

BAG-1, BAG-1N, BAG-1M and BAG-1L

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

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all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

BAG-1: Claims 51-88

BAG-1N: Claims 51-88

BAG-1M: Claims 51-88

BAG-1L: Claims 51-88

The following claim(s) are generic: Claims 51-88.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the special technical feature linking the species appears to be the BAG protein isoforms. The BAG protein isoforms cannot be a special technical feature under PCT Rule 13.2 because it is shown by Krajewski et al (Endocrine-related cancer, Mar.6(1): 29-40, 1999, IDS) in the prior art. Krajewski et al. teach the BAG protein isoforms BAG-1, BAG-1M, BAG-1L (see page 34, right column), therefore the technical feature linking the species is not novel and does not provide contribution over the prior art. Therefore, unity of invention is lacking and the species are deemed to be separate.

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6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hong Sang  
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Aug. 15, 2005

  
CHRISTOPHER YAEN  
PATENT EXAMINER